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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/497,591 02/03/00 NELSESTUEN

G 09531-016001

HM12/0328

EXAMINER

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ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/497,591</b>	Applicant(s) <b>Netsestuen</b>
	Examiner <b>F. T. Moezie</b>	Group Art Unit <b>1653</b>

Responsive to communication(s) filed on Feb 3, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-60 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-60 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### **STATUS OF THE CLAIMS**

Claims 1-60 are pending in this application.

### **RESTRICTION REQUIREMENT**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 8-14, drawn to a substitution-modified Protein C or Activated Protein C, classified in class 530, subclass 384, for example.
- II. Claims 15-17, drawn to an active site substitution-modified Factor VIIa polypeptide , classified in class 530, subclass 384, for example.
- III. Claims 18-23, drawn to a substitution-modified Protein S polypeptides, classified in class 530, subclass 380, for example.
- IV. Claims 24-27, drawn to an active site substitution-modified Factor IXa, classified in class 530, subclass 384, for example.
- V. Claims 28-30, drawn to a substitution-modified Factor VII, classified in class 530, subclass 384, for example..
- VI. Claims 31-33, drawn to a substitution-modified Factor Xa, classified in class 530, subclass 384, for example.
- VII. Claims 34-36, drawn to a substitution-modified Protein Z, classified in class 530, subclass 380, for example.

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- VIII. Claims 37-40, drawn to an insertion-modified polypeptide by an amino acid insertion at amino acid 4, classified in class 530, subclass 380, for example.
- IX. Claim 51, drawn to a mammalian host cell comprising a vitamin K-dependent polypeptide, classified in class 435, subclass 325, for example.
- X. Claims 52-56, drawn to a method of decreasing clot formation using a modified GLA domain vitamin K-dependent polypeptide, classified in class 514, subclass 2, for example.
- XI. Claims 57-60, drawn to a method for identifying a vitamin K-dependent polypeptide, classified in class 460, subclass 2, for example.

- 1. The inventions are distinct, each from the other because of the following reasons:
- 2. Inventions I, II, III, IV, V, VI or VII and VIII are distinct one from the other. Inventions are distinct because each class of polypeptides has its own unique structure and thereby its own physical/chemical and pharmaceutical properties. Therefore, each invention requires a separate search and consideration of patentability. Moreover, a reference which would obviate claims drawn to one of the inventions may not render claims drawn to the other inventions - absent ancillary evidence. It would be an undue burden to examine all of the inventions in one application.

Any of Inventions I to VIII and IX are distinct one from the other. Inventions are distinct they have different objectives, different effects and different modes of operation.

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3. Inventions I, II, III, IV, V, VI, VII or VIII and X or XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case any of the products can be used in a process for treating a patient or in a process of identifying a polypeptide as shown above.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Upon finding allowable subject matter in any one of the inventions I to VII, claims 1-7 will be considered in a rejoinder, provided that the claims are rewritten commensurate in scope with the allowable claims.

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**ELECTION OF SPECIES**

Claims 1-60 are generic to plurality of disclosed patentably distinct species comprising:

The substitution-modified GLA domain of Factors VII or VIIa, IX, Xa, Protein C, S, Z; ,

The insertion-modified Factor VII or VIIa, protein C or Activated Protein C, Factor X or Factor Xa and Protein S.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and an ultimate specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**An Ultimate specie of a compound is a compound wherein all of its variable parameters are accounted for.**

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon within the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**REQUIREMENTS FOR THE AMINO ACID SEQUENCE DISCLOSURES NOT  
FULLY MET**

The amino acid sequence disclosure filed by applicant has been entered into the data base on 29 March 2000. However, the compliance with the requirement is incomplete because:

**UPON COMPLIANCE WITH THE REQUIREMENTS APPLICANT MUST  
ALSO AMEND THE APPLICATION TO PROVIDE SEQ ID NOS IN THE  
SPECIFICATION (AT LEAST IN THE FIRST OCCURANCE), IN ALL EXAMPLES,  
TABLES AND THE CLAIMS.**

Unless the SEQ IDS are identified the particular amino acid position(s) cited in the claims find no basis in the modified-polypeptide being claimed and results in incomplete search.

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Any inquiry concerning this communication should be directed to F.T. Moezie at  
telephone number (703) 305-4508, FAX (703) 305-7401.

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PTI INTL INC